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Performance Characteristics of Seven Bilevel Mechanical Ventilators in Pressure-Support Mode with Different Cycling Criteria: A Comparative Bench Study

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

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Background: Pressure support ventilation from a bilevel device is a standard technique for non-invasive home ventilation. A bench study was designed to compare the performance and patient-ventilator synchronization of 7 bilevel ventilators, in the presence of system leaks.





Material/Methods: Ventilators were connected to a Hans Rudolph Series 1101 lung simulator (compliance, 50 mL/cmH₂O; expiratory resistance, 20 cmH₂O/L/s; respiratory rate, 15 breaths/min; inspiratory time, 1.0 s). All ventilators were set at 15 cmH₂O pressure support and 5 cmH₂O positive end-expiratory pressure. Tests were conducted at 2 system leaks (12–15 and 25–28 L/min). The performance characteristics and patient-ventilator asynchrony were assessed, including flow, airway pressure, time, and workload.

Results: The Breas Vivo30 could not synchronize with the simulator (frequent auto-triggering) at a leak of 25–28 L/min, but provided stable assisted ventilation when the leak was 12–15 L/min. Missed efforts and back-up ventilation occurred for the Weinmann VENTImotion and Airox Smartair Plus, requiring adjustment of trigger effort. All ventilators had a short trigger delay time (<200 ms), but significant differences between devices were found in triggering workload, pressurization appearance, tidal volume, and peak inspiratory flow. Premature cycling was frequent when the inspiratory termination criteria were at the highest sensitivity. Cycling synchronization was considerably improved by modifying expiratory triggering sensitivity settings, when available.

Conclusions: Performance and triggering workload varied significantly between bilevel ventilators, possibly due to software algorithm differences. Adjusting the cycling criteria settings can alter the shape of the inspiratory phase and peak expiratory flow, and improve patient-ventilator synchrony.

MeSH Keywords: **Air Pressure • Continuous Positive Airway Pressure • Lung • Respiratory System • Ventilators, Mechanical**

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Background

Non-invasive positive-pressure ventilation (NPPV), delivered via a nasal or full-face mask, is a well-established treatment that is being increasingly used for patients with hypercapnic respiratory failure (HRF) due to chronic obstructive pulmonary disease (COPD). NPPV can reduce the need for intubation, shorten hospitalization times, and improve outcomes by lowering the rates of complications and mortality [1–3]. Although any mechanical ventilator may be used to perform NPPV, some ventilators are designed specifically to provide non-invasive ventilation [4]. Pressure support ventilation (PSV) has become the ventilatory mode of choice when NPPV is performed. An important advantage of PSV is the ability to adjust the sensitivity and cycling criteria [5,6]. During NPPV, air-leaks around the mask are unavoidable, and this can affect patient-ventilator synchrony [7]. For adequate leak compensation, the ventilator should automatically and rapidly respond to changes in leak flow during triggering and cycling.

Several recent trials have demonstrated that bilevel pressure ventilators perform better than critical care ventilators in terms of patient-ventilator synchrony and leak compensation [8–10]. However, there is a lack of published research assessing the performance of bilevel ventilators in China. In this bench study, we have utilized a lung simulator, set to mimic the respiratory mechanics of a patient with moderate-to-severe COPD, to compare the performance and synchronization of the 7 bilevel devices most commonly used in China. Our study found that although almost all the bilevel ventilators function adequately but some devices had better performance and synchronization.

Material and Methods

Stimulator settings

The stimulator setting was according to the work of Ferreira et al. with some modifications [10]. The Series 1101 Lung Simulator (Hans Rudolph Inc., Shawnee, KS, USA) is a computerized lung simulator consisting of a piston that moves inside a cylinder. The compliance, resistance, and inspiratory muscle pressure profile (negative pressure created by the respiratory muscles) may be set by the user. The simulator was adjusted to simulate a patient with moderate-to-severe COPD [11,12]. The following settings were used: compliance, 50 mL/cmH₂O; expiratory resistance, 20 cmH₂O/L/s; inspiratory time, 1.0 s; maximum inspiratory pressure drop, –5 cmH₂O; pressure drop generated 300 ms after the onset of an occluded inspiratory effort, –3.6 cmH₂O; and respiratory rate, 15 breaths/min [13]. The Series 1101 simulator incorporates 2 user-controlled leaks: an exhalation hole (internal diameter

[ID], 2.0 mm) and a plateau exhalation valve (PEV). For this experiment, the leak flows were set at 12–15 and 25–28 L/min at a peak airway pressure of 20 cmH₂O, using different exhalation valves [14,15]. All measurements were performed at an inspired oxygen fraction (F_IO₂) of 0.21.

A mannequin head was used to simulate the patient-mask interface. Endotracheal tubes (ID, 22 mm) fitted into the mouth and nostrils were used to direct gas coming from the facemask to the simulator. A medium-sized oronasal facemask without an exhalation port (BestFit™; Curative Medical Inc, Santa Clara, CA, USA) was affixed tightly to the head of the mannequin with standard straps. A leak of 1–2 L/min was measured at 20 cmH₂O of positive pressure when the exhalation hole or PEV were removed.

Ventilator settings

Seven bilevel ventilators were compared using the lung simulator with system leaks: Vision and Synchrony (Respironics; Murrysville, PA, USA); VENTImotion (Weinmann; Hamburg, Germany); VPAP III ST-A (ResMed; North Ryde, Australia); Flexo ST 30 (Curative Medical Inc, Santa Clara, CA, USA); Vivo 30 (Breas Medical AB; Mölnlycke, Sweden) and SmartAir Plus (Airox; Pau, France) (Table 1). Each ventilator evaluated was connected to the lung simulator by a standard disposable corrugated circuit (length, 2.0 m). All the ventilators were studied with a dry circuit; humidifiers and heat and moisture exchangers were removed.

All the ventilators were set in PSV mode as follows: positive end-expiratory pressure (PEEP), 5 cm H₂O; pressure support level, 15 cmH₂O; back-up respiratory rate, 10 breaths/min; maximal duration of the inspiratory phase, 1.5 s. The trigger sensitivity was set to be as sensitive as possible while avoiding auto-triggering. The inspiratory rise time was set to 100 ms, or the most rapid setting (90 ms for the VPAP III ST-A ventilator). The inspiratory termination criteria, when adjustable, were set to the most sensitive level. During data collection, trigger sensitivity and inspiratory effort were adjusted as leaks were introduced into the system, to avoid simulator-ventilator asynchrony (auto-triggering or back-up ventilation).

Data collection

Once the baseline pressure had stabilized, air leaks generated by the exhalation hole or PEV were added sequentially to the system. At least 5 min was allowed for the ventilator to synchronize with the simulator. If synchronization did not occur, changes in sensitivity, inspiratory effort, or both were made and recorded. If synchronization was not achieved, the ventilator was considered to be unable to provide assisted ventilation at the level of the leak. In all cases, failure to synchronize

Table 1. The main characteristics of the seven bilevel devices tested.

Ventilator	Leak compensation (L/min)	Inspiratory trigger (L/min)	IPAPmax/PSmax (cmH ₂ O)	Rise time/slope (ms)	Expiratory trigger (L/min)	EPAP/PE-EPmin (cmH ₂ O)
Respironics vision	60	Automatic	40	50–400	Auto	4
Respironics synchrony	60	Automatic	30	100–600	Auto	4
ResMed VPAP III ST-A	NA	3 sensitivity settings	30	90–900	3 sensitivity	2
Weinmann	NA	(2.5/4.0/7.5 L/min)	35	1–6 AU	Settings	4
VENTImotion	NA	1–6 AU	30	1–4 AU	Off/1–6 AU	4
Airox SmartAir ST	NA	1–5 AU	30	1–9 AU	Auto/15–75% of PIF	2
Breas Vivo 30	60	1–9 AU	30	1–6 AU	1–9 AU	4
Curative Flexo ST 30		1–6 AU		50/80/100/ 200/300/400	1–6 AU	

AU – arbitrary units; PEEPmin – minimum level of positive end-expiratory pressure that can be set on the device; PSmax – maximum pressure support that can be set on the device; rise time/slope: possible settings for the slope of the pressurization (the lower the number, the steeper the slope).

resulted in rapid auto-triggering or an inability to trigger. After stabilization, 6 representative breaths were collected at a sampling interval of 1 min. Offline analysis of each breath was performed by using Series 1101 lung simulator software.

Inspiratory triggering, triggering workload, and expiratory cycling were evaluated, as these parameters represent the main determinants of the patient-ventilator interaction [16]. Specific aspects of these 3 parameters were assessed (Figure 1).

The following parameters were assessed for inspiratory triggering: the triggering delay (Td), defined as the time between the onset of the inspiratory effort and the onset of detectable pressurization; and the inspiratory pressure-time product (PTPt), measured as the area under the pressure-time curve between the onset of the inspiratory effort and the return to atmospheric pressure or the preset PEEP.

For the inspiratory phase, the peak inspiratory flow (PIF), peak airway pressure (Pawhigh), duration of airway pressure above 90% of the preset support pressure level (Ti plat), and pressure at the end of the inspiratory effort of the ventilator (Pi end) were determined. The tidal volume was monitored by the simulator (Vt simulator).

Inspiratory/expiratory cycling was assessed from the peak expiratory flow (PEF) and the cycling delay time (Cdelay). Cdelay was measured as the time from the end of the inspiratory effort of the simulator to the moment that the ventilator cycled from inspiration to expiration; a negative value reflects premature

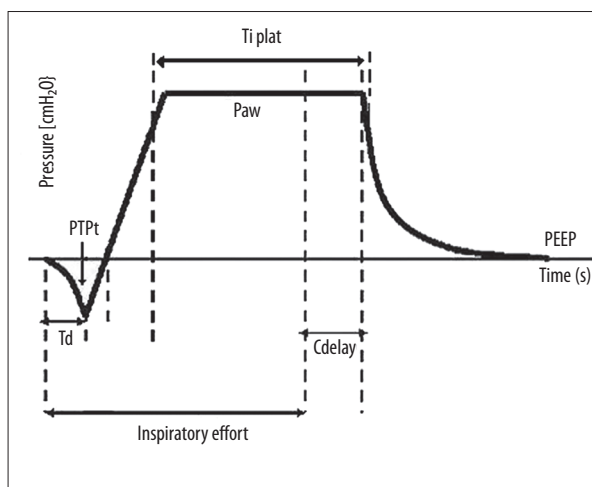


Figure 1. Depiction of the variables measured from the pressure-time curves of the bilevel ventilators tested. Paw = the value of the airway pressure; Td = the time between the onset of the inspiratory effort and the onset of detectable pressurization; PTPt = the area under the pressure-time curve between the onset of the inspiratory effort and the return to PEEP; Ti plat = the duration of airway pressure above 90% of the preset support pressure level; Cdelay = the time from the end of the inspiratory effort of the simulator to the moment the ventilator cycles from inspiration to expiration.

interruption of pressurization (premature cycling), and a positive value reflects a duration of pressurization exceeding that of the patient's inspiratory effort (delayed cycling) [17].

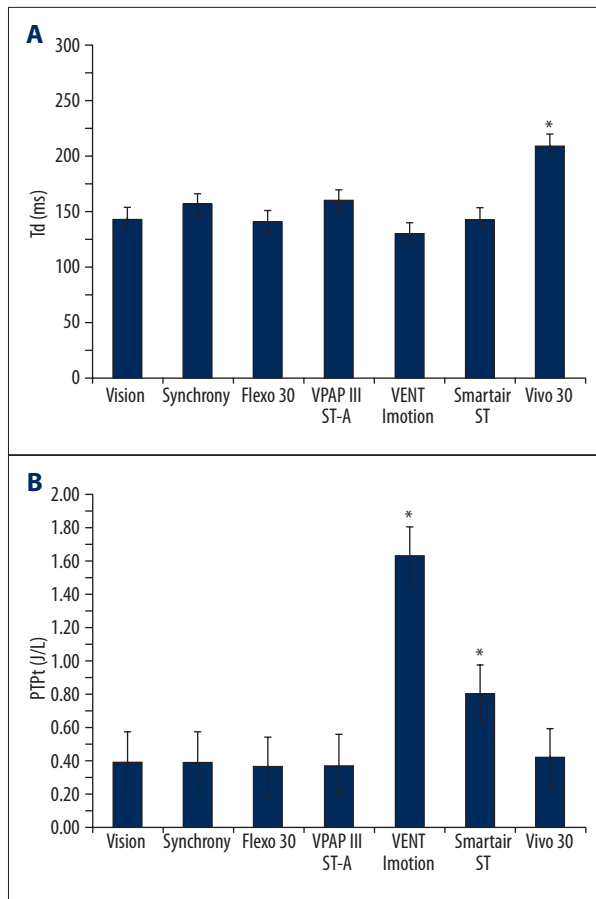


Figure 2. Comparisons of the inspiratory trigger delay time (Td) and workload (PTPt) values for the 7 bilevel ventilators, tested at an inspiratory effort of 5–20 cmH₂O. Data are plotted as the mean ±SD. * $P < 0.05$ vs. the Vision, Synchrony, and Flexo ST 30 ventilators.

Statistical analysis

Data are presented as the mean ± standard deviation (SD). Statistical analysis was carried out using the SPSS version 11.0 (SPSS; Chicago, IL, USA) statistical software package. Comparisons of the results between the various ventilators were undertaken using analysis of variance by ranks. Comparisons of variables at different cycling sensitivity settings were made using Student's t-test. A value of $P < 0.05$ was considered as statistically significant.

Results

Performance with a system leak

The Vision, Synchrony, Flexo ST 30, and VPAP III ventilators were able to adapt to the system leak (25–28 L/min) without requiring adjustment, but the Vivo 30 ventilator required

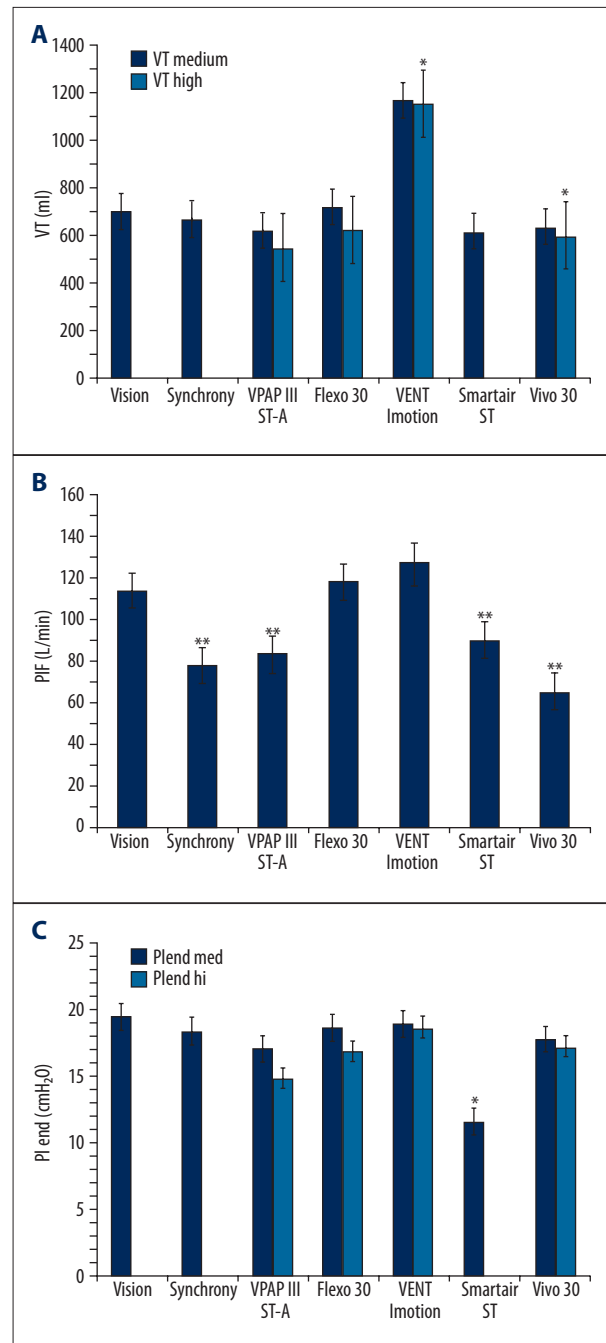


Figure 3. Comparisons of the inspiratory volumes, flows, and pressures of the 7 bilevel ventilators, tested at high and medium expiratory trigger sensitivity settings. Data are plotted as the mean ±SD. * $P < 0.05$ vs. the Vision, Synchrony, and Flexo ST 30 ventilators (with moderate expiratory sensitivity); ** $P < 0.05$ vs. the Vision and Flexo ST 30 ventilators.

auto-triggering to achieve synchrony until the leak level was decreased to 12–15 L/min. The VENTImotion and Smartair Plus ventilators were unable to synchronize with the inspiratory

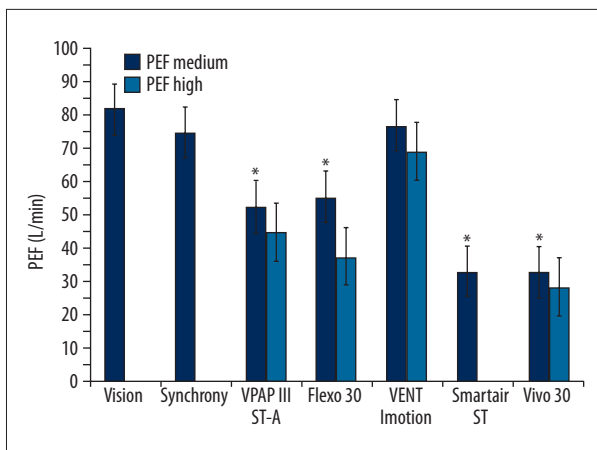


Figure 4. Comparisons of the PEF values for the 7 bilevel ventilators, tested at high and medium expiratory trigger sensitivity settings. * $P < 0.05$ vs. the Vision, Synchrony, and VENTImotion ventilators (with moderate expiratory sensitivity).

effort and resorted to back-up ventilation. The Smartair Plus and VENTImotion ventilators were able to synchronize stably after the inspiratory effort was changed to -10 or -20 cmH_2O .

Inspiratory triggering

The T_d was < 200 ms for all machines, except for the Vivo 30 (209.00 ± 7.43 ms). Four devices, including the Vision, Flexo ST 30, VENTImotion and Smartair Plus, all had a mean T_d of < 150 ms. PT_{Pt} reflects the inspiratory work required to trigger the ventilator; therefore, the lower its value, the smaller the work required of the inspiratory muscles [9,18]. For an inspiratory effort of -5 cmH_2O , PT_{Pt} was similar for 5 machines but significantly higher in the other 2 (VENTImotion and Smartair Plus). The negative pressure deflections preceding the response by the device averaged between 0.25 and 0.82 cmH_2O (Figure 2).

Inspiratory tidal volume, flow and pressure

The V_t monitored by the simulator was smallest for the Smartair Plus ventilator (614.50 ± 5.75 mL), greatest for the VENTImotion ventilator (1167.50 ± 13.95 mL), and approximately 750 mL for the Flexo ST 30. The PIF was above 100 L/min for the VENTImotion, Flexo ST 30 and Vision ventilators, and was lowest for the Vivo 30 device (65.17 ± 1.47 L/min). PEF was highest for the Vision (82.03 ± 2.83 L/min) and VENTImotion (76.85 ± 0.67 L/min) ventilators (Figures 3 and 4). The preset support pressure was reached for all the devices, but the pressure-time curves and the P_i end varied considerably (Figures 3 and 5)

Inspiratory/expiratory cycling

Cycling varied markedly among the 7 machines, and was influenced by which inspiratory termination criteria were used. The 2 machines with automatic cycling settings – the Vision and Synchrony ventilators – tended to delay cycling under obstructive conditions. $T_{i, plat}$ and C_{delay} were longest for the Vision device, whereas the Flexo ST 30, VPAP III, Smartair Plus, and Vivo 30 ventilators cycled prematurely; $T_{i, plat}$ was shortest for the Smartair Plus (233.33 ± 9.00 ms) (Figure 6).

Changing cycling sensitivity

Of the 4 devices with adjustable inspiratory termination criteria, the Flexo ST 30 showed delayed cycling at moderate sensitivity, and $T_{i, plat}$ was increased from 517.17 ± 16.44 ms to 847.50 ± 10.71 ms ($P < 0.05$) (Figure 6).

Discussion

The main findings of this study are that, at a system leak level of 25 – 28 L/min, all the ventilators assessed, except for the

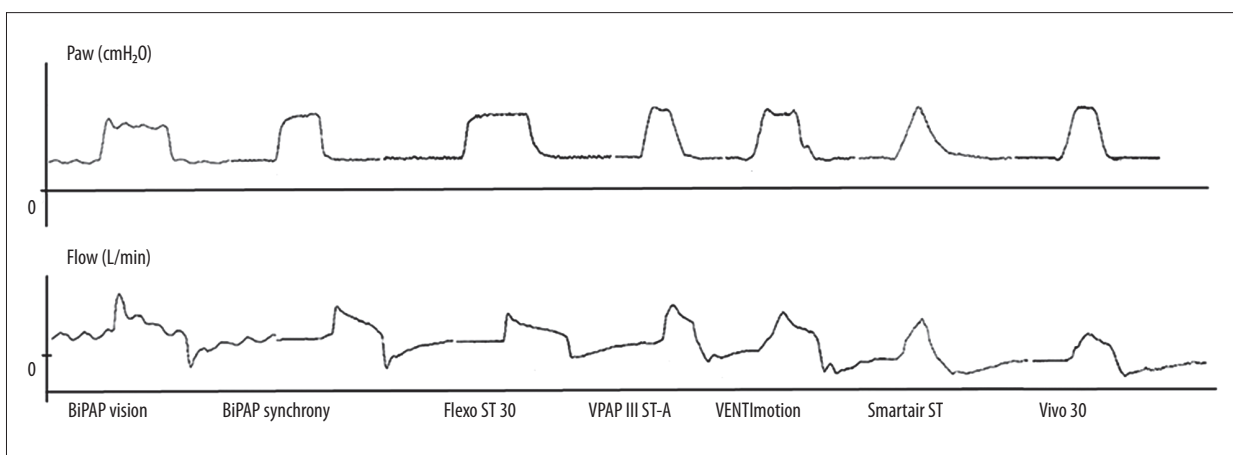


Figure 5. Pressure-time and flow-time curves for the 7 bilevel ventilators, tested at a pressure support level of 15 cmH_2O and a PEEP level of 5 cmH_2O .

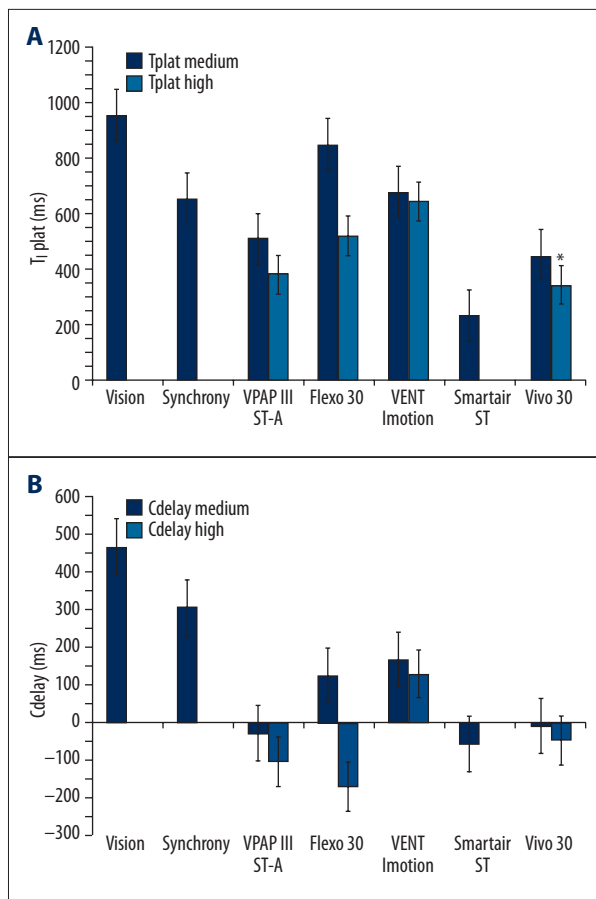


Figure 6. Comparisons of the inspiratory inflation times (T_{iplat}) and cycling delay times (C_{delay}) of the 7 bilevel ventilators, tested at high and medium expiratory trigger sensitivity settings. * $P < 0.05$ vs. the Vision and Flexo ST 30 ventilators (with moderate expiratory sensitivity).

Vivo 30, were able to deliver adequate tidal volume, reach the preset support pressure level, and synchronize with the simulator, without the occurrence of missed efforts or auto-triggering. In addition, delayed cycling occurred with the Vision and Synchrony devices due to their auto-tracking sensitivity technique [19], while the other ventilators (except for the VENTImotion) exhibited premature cycling when the inspiratory termination criteria were set at the most sensitive level. Furthermore, significant differences in the pressure-time curves were observed between the 7 devices, and high PEF was associated with a prolonged inspiratory phase.

The biggest limitation of critical care ventilators is that it is difficult to deal with the leak that inevitably occurs during non-invasive ventilation. Indeed, only a few modern ventilators can provide near-perfect non-invasive ventilation [10]. Mehta et al. observed that the capabilities of leak compensation differed considerably between various ventilators, with bilevel

ventilators providing better compensation for leaks than some volume-controlled ventilators, through an increase in inspiratory flow [20]. Bilevel ventilators are specially designed for home care, and have been used to provide non-invasive ventilation for more than 2 decades. Patients receive positive-pressure ventilation via a mask with an existing air leak, and leak compensation may be activated by increasing the inspiratory flow or volume. Typical ventilation modes include PSV, pressure-controlled ventilation (PCV), and continuous positive airway pressure (CPAP). Evaluations of these ventilation modes have concluded that they perform as well as, and sometimes better than, critical care ventilators [21–25]. One concern with bilevel pressure ventilators is the potential for CO_2 rebreathing, because the devices use a single hose that does not contain a true exhalation valve [18,26,27]. This problem may be resolved by using fixed-leak equipment (e.g., a hole or simple valve that is established in the device system) that allows expired gas to pass through in order to limit rebreathing. Stell et al. found that an exhalation port with an orifice of 2 mm increased the leak to approximately 12 L/min with a mask pressure of 20 cmH_2O , and that a larger leak of approximately 25 L/min was achieved with an exhalation port diameter of 4 mm [8]. Excessive leakage can delay triggering and cycling, decrease the tidal volume, and aggravate patient-ventilator asynchrony. In our bench study, a PEV was used because its leak level is stable (25–28 L/min) in the face of changes in inspiratory pressure and/or expiratory pressure. Some clinical studies have reported that the use of a PEV can eliminate CO_2 rebreathing during NPPV [28,29].

Trigger synchrony is critical for non-invasive ventilation. Battisti et al. compared the performance characteristics of 10 home mechanical ventilators, in PSV mode and in the presence of leaks (6–8 L/min), using a lung model set to mimic normal, obstructive, and restrictive conditions; a shorter trigger delay and smaller triggering workload were observed [9]. In the present bench study, neither the VENTImotion nor the Smartair Plus ventilators were able provide assisted ventilation at an inspiratory effort of 5 cmH_2O , and the triggering workload of these devices was also higher than that of the others, due to the larger inspiratory effort.

In this study, markedly delayed cycling was observed for the Vision and Synchrony ventilators, which transition to exhalation primarily by a “shape signal”. The shape signal is offset from the actual flow of the patient by 15 L/min and is delayed by 300 ms – when the patient’s inspiratory flow crosses the shape signal, the ventilator cycles to exhalation [19].

Another important observation was that significant differences existed in V_T and PIF between ventilators during PSV, despite the same settings being used for the respiratory mechanics of the simulator. We can infer that these are due to differences in

the designs of the machines, and their inspiratory efforts and expiratory trigger settings. Louis et al. compared the effects of masks with different manufacturer-inserted leaks on ventilator performance: differences in V_T were observed under obstructive disease conditions, with some ventilators delivering a V_T that was 1000 mL larger than that *in vivo*, when the peak pressure was set to 18–20 cmH₂O and PEEP was 3–4 cmH₂O [30]. Similarly, our study revealed that V_T exceeded 1000 mL for the VENTImotion device, while the volumes delivered by the Vision and Flexo ST 30 ventilators were above 700 mL and approached the theoretical value (750 mL; $V_T = Crs \times P$). We assume that the differing behavior of these ventilators is at least in part due to differences in the ventilator software, particularly the design of the algorithm used to drive the machine to deliver positive-pressure ventilation [9,10,31].

An additional important difference in the performance of bilevel ventilators has been highlighted recently by Contal et al. [32]. Their bench study of 7 devices revealed great variability in the reliability with which the ventilator software estimated leaks and V_T . This emphasizes the importance of selecting a ventilator with performance characteristics best suited to the needs of the individual patient [33].

Several limitations of this study should be noted. First, during the bench study, only moderate-to-severe obstructive disease was simulated, because the respiratory mechanics are known to affect the cycling delay. However, premature cycling was found in some devices. Second, only 2 levels of system leak were investigated, which may not reproduce what happens under

clinical conditions. Nevertheless, our study demonstrated that all the selected ventilators, except for the Vivo 30, succeeded in providing assisted ventilation in the presence of the leak.

Conclusions

All the bilevel ventilators, except for the Vivo 30, adequately delivered NPPV at a system leak of 25–28 L/min in a lung model simulating a patient with moderate-to-severe COPD. Some devices, such as the Vision and VENTImotion ventilators, showed better trigger synchrony, a higher inspiratory flow, and sufficient inflation time. By adjustment of the inspiratory termination criteria, the Flexo ST 30 exhibited better performance and synchronization. Attention should be given to the differences in the pressure-time curves between the ventilators, as this may influence the comfort of the patient and patient-ventilator synchrony.

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Conflict of interest

The authors confirm that there are no conflicts of interest to declare.

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